FILED

08 MAR 28 PM 2:47

CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

BY: cf DEPUTY

LISA L. HALKO (SBN 148873)
KATHLEEN E. FINNERTY (SBN 157638)
GREENBERG TRAURIG, LLP
1201 K Street, Suite 1100
Sacramento, CA 95814-3938
Telephone: (916) 442-1111
Facsimile: (916) 448-1709
halkol@gtlaw.com

Attorneys for Defendants
Synthes Spine Company, L.P. and Spine Solutions, Inc.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

BY FAX

CALVIN TIMBERLAKE and KAREN TIMBERLAKE, Plaintiffs, vs. SYNTHES SPINE COMPANY, L.P. Defendant	CASE NO. '08 MC 0157 **DEFENDANT SYNTHES SPINE COMPANY, L.P.'S BRIEF IN SUPPORT OF ITS MOTION TO QUASH OR, IN THE ALTERNATIVE, STAY PLAINTIFFS' THIRD-PARTY SUBPOENA ON TIMOTHY A. PEPPERS, M.D. AND CORE ORTHOPEDIC MEDICAL CENTER**

COMES NOW Defendant Synthes Spine Company, L.P. ("Synthes") and files this Brief in Support of its Motion to Quash or, in the alternative, Stay Plaintiffs' Third-Party Subpoena Issued on Timothy A. Peppers, M.D. and CORE Orthopedic Medical Center pursuant to Rule 45(c)(3) of the Federal Rules of Civil Procedure. COMES NOW Defendant Synthes Spine Company, L.P. ("Synthes") and files this Brief in Support of its Motion to Quash or, in the alternative, Stay Plaintiffs' Third-Party Subpoena Issued on Jim Zucherman, M.D. pursuant to Rule 45(c)(3) of the Federal Rules of Civil Procedure.

Although this case is pending in the Southern District of Texas, the subpoena was issued by this Court, as the "issuing court" under Rule 45(c)(3)(A), the correct venue for this motion. *Fincher v. Keller Industries* 129 F.R.D. 123, 125 (M.D. NC 1990).

ORIGINAL

CR

For the reasons set forth below, Synthes requests that the Court quash the subpoena or, alternatively, stay any required disclosures under the subpoena until after the parties' home district rules on Defendant's Motion for Protective Order, because the subpoena seeks information that is irrelevant, overly broad, privileged and confidential, and was served to unduly burden Synthes.

FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs Calvin Timberlake and Karen Timberlake ("Plaintiffs") filed their First Amended Original Complaint ("Amended Complaint") in this alleged products liability action currently pending in the U.S. District Court for the Southern District of Texas, Victoria Division, Civil Action No. 6:08-CV-00004 on February 21, 2008.[1] Plaintiffs' Amended Complaint asserts claims of negligence, strict liability, breach of warranty, fraud/misrepresentation, and conspiracy arising out of the implantation of the ProDisc artificial disc device, distributed by and manufactured on behalf of Synthes, in Plaintiff Calvin Timberlake. In addition, Plaintiffs' Amended Complaint named as additional defendants Spine Solutions, Inc., Viscogliosi Brothers, L.L.C., Marc R. Viscogliosi, John J. Viscogliosi, and Anthony J. Viscogliosi. Synthes filed its Answer to Plaintiffs' First Amended Original Complaint and Motion to Dismiss or in the Alternative to Transfer Venue on March 13, 2008. Upon information and belief, Defendants Viscogliosi Brothers, L.L.C., Marc R. Viscogliosi, John J. Viscogliosi, and Anthony J. Viscogliosi, however, have not yet been served with Plaintiffs' Amended Complaint, nor have they filed a responsive pleading. Counsel for Defendant Spine Solutions, Inc. accepted service of Plaintiffs Amended Complaint and will timely file its responsive pleading on or before March 31, 2008.

The very same day that Synthes filed its responsive pleadings, Plaintiffs issued ten third-party subpoenas for production and inspection of documents, including the third-party subpoena on Timothy A. Peppers, M.D. ("Dr. Peppers") and CORE Orthopedic Medical Center (the "Subpoena").[2] Plaintiffs improperly issued the Subpoena before all of the Defendants have

---

1 A true and correct copy of Plaintiffs' First Amended Original Complaint is attached hereto as Exhibit A.

2 A true and correct copy of the subpoena is attached hereto as Exhibit B.

answered the Amended Complaint and long before discovery has commenced, or has been discussed at the required Rule 26(f) conference.

The third parties to whom the Subpoena was issued, Dr. Peppers and CORE Orthopedic Medical Center (collectively the "Third-Parties"), are not parties to this case and are in no way related to the care and treatment of Plaintiff Calvin Timberlake. Rather, Dr. Peppers was a clinical investigator in the FDA-approved clinical trial of the ProDisc prior to its pre-market approval ("PMA") by the Food and Drug Administration ("FDA"). Plaintiff Calvin Timberlake, however, was not a participant in the FDA-approved clinical trial and was not implanted with the ProDisc device until after its pre-market approval by the FDA. Further, upon information and belief, Plaintiff Calvin Timberlake has never received treatment from Dr. Peppers or Core Orthopedic Medical Center.

Plaintiffs' Subpoena requests that the Third-Parties produce voluminous, irrelevant documents. Specifically, in the Subpoena, Plaintiffs seek, *inter alia*, "all documents," with no limit in time or scope to the care and treatment of Plaintiff Calvin Timberlake, including studies, test plans, data, reports, results, conclusions, accounting records, bills, charts, drawings, agreements, communications, correspondence, faxes, summaries of records or telephone conversations, minutes or records of meetings or conferences, lists of persons attending meetings or conferences, bank records, and all other writings concerning:

> 1. All documents relating to your investment, or potential investment in any company or entity known to you or believed by you to have any relationship, ownership, or other involvement with the ProDisc, including but not limited to any correspondence, solicitations, investor packets, stock certificates, ownership certificates, shareholder agreements, and loan documents.
>
> 2. All financial documents relating to your investment in, purchase or sale of your investment in any company or entity known to you or believed by you to have any relationship, ownership or other involvement with the ProDisc, including but not limited to bank records, canceled checks, income tax returns, and loan documents.
>
> 3. All documents relating to any agreements with any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc, to perform, clinical trials or other trials relating to the ProDisc.

> 4. All financial documents pertaining to your agreement with any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc, to perform clinical trials or other trials on the ProDisc.
>
> 5. All documents relating to your relationship with Synthes, Inc. or any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc, including but not limited to stock ownership, and agreements to market, sell or implant ProDisc.
>
> 6. All documents you filed with or provided to the Food and Drug Administration that discuss mention or in any way relate to ProDisc.
>
> 7. All documents filed with or provided to the FDA that discloses, discusses or denies that you have or had an ownership interest in any company or entity known to you or believed by you to have any relationship, ownership, or other involvement with ProDisc that has or had a financial interest in ProDisc.
>
> 8. All correspondence between you and the FDA that relate in any way to ProDisc.
>
> 9. All correspondence that relates to ProDisc between you and any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc.

Plaintiffs' Subpoena, Exhibit B.

Synthes objects to each of the nine requests for production of documents specified in the Subpoena on the grounds that the requests (1) are overly broad and unduly burdensome; (2) seek irrelevant information and are not reasonably calculated to lead to the discovery of admissible evidence; (3) seek Synthes' confidential proprietary and trade secret information; and (4) are in violation of the privacy regulations issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and state privacy law regarding individuals' protected health information. Accordingly, Plaintiffs' burdensome and oppressive Subpoena should be quashed.[3]

---

[3] Additionally, in accordance with FED.R.CIV.P. 26(c), Synthes has moved for a protective order regarding the specific information sought by Plaintiffs' third party subpoena in the U.S. District Court for the Southern District of Texas, Victoria Division. Synthes respectfully requests that this Court stay any ruling on this Motion until the Court where this matter is pending rules on Synthes' Motion for Protective Order.

ARGUMENT AND CITATION OF AUTHORITY

A. Standard for a Motion to Quash

Synthes timely files this Motion to Quash in accordance with Rule 45 of the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 45(c)(3)(A); *Anderson v. Abercrombie and Fitch Stores, Inc.*, No. 06 CV 991, 2007 WL 1994059, at *2 (S.D. Cal. July 2, 2007) (explaining that the non-party served with a subpoena "may make objections to the subpoena within fourteen days after service, or before the time for compliance if less than fourteen days[,]" and that a party cannot object to a subpoena but must move to quash or seek a protective order).

Rule 45(c)(3)(A) of the Federal Rules of Civil Procedure authorizes the Court from which a subpoena was issued to quash a subpoena that "requires disclosure of privileged or protected matter" or "subjects a person to undue burden." *See Premium Service Corp. v. Sperry & Hutchinson Co.*, 511 F.2d 225, 229 (1975) ("A district court may quash a subpoena duces tecum, the results of which it finds 'unreasonable and oppressive'"). Interpreting this Rule, courts have allowed parties to move to quash third party subpoenas under Rule 45 on the grounds that the information sought is not relevant to the subject matter of the action. *See Mattel Inc. v. Walking Mountain Productions*, 353 F.3d 792 (9th Cir. 2003); *Premium Serv. Corp. v. Sperry & Hutchinson Co.*, 511 F.2d 225 (9th Cir. 1975); *Anderson v. Abercrombie and Fitch Stores, Inc.*, No. 06 CV 991, 2007 WL 1994059 (S.D. Cal. July 2, 2007); *Trunk v. City of San Diego*, No. 06 CV 1597, 2007 WL 2701356 (S.D. Cal. Sept. 13, 2007). Further, "[t]o protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires disclosing a trade secret or other confidential research, development, or commercial information . . . ." FED. R. CIV. P. 45(c)(3)(B). Here, the Subpoena both requires disclosure of protected information and subjects Synthes and the subpoenaed Third-Parties to undue burden. Thus, this Court should quash the Subpoena and prevent the disclosure of the confidential information.

Furthermore, Synthes specifically has standing to file this Motion to Quash the Subpoena which seeks the production of confidential and proprietary information.. A court may quash or modify a subpoena to protect a person subject to *or affected by* the subpoena if the subpoena subjects the person to undue burden and costs or seeks disclosure of a trade secret or other confidential information. Fed. R. Civ. P. 45(c)(3)(B). *See also Anderson v. Abercrombie and Fitch Stores, Inc.*, No. 06 CV 991, 2007 WL 1994059, at * 2 (S.D. Cal. July 2, 2007) ("A party cannot simply object to a subpoena served on a non-party, but rather must move to quash or seek a protective order.").

B. Plaintiffs' Subpoena Is Overly Broad and Unduly Burdensome.

Plaintiffs' third-party discovery requests are overly broad and unduly burdensome. The breadth of Plaintiffs' requests place undue burden upon both Synthes and the subpoenaed third-parties. Plaintiffs seek the production of virtually any and all documents related to ProDisc that may be in the Third-Parties' possession, ranging from personal financial information of the Third-Parties, to health information of patients treated by the Third-Parties in the clinical trial of ProDisc, to proprietary clinical trial design, protocol, and implementation documents, to all communication between the Third-Parties and anyone at any time involved in any way with the ProDisc. Plaintiffs make no attempt whatsoever to limit their requests in time or scope of the pending action. The sheer breadth of Plaintiffs' Subpoena without any attempt to tailor the requests to the pending litigation is oppressive and unduly burdensome to both Synthes and the Third-Party recipients. *See Anderson v. Abercrombie and Fitch Stores, Inc.*, No. 06 CV 991, 2007 WL 1994059, at * 2 (S.D. Cal. July 2, 2007) ("[A] subpoena is unduly burdensome where it seeks to compel production of documents regarding topics unrelated to or beyond the scope of the litigation.").

C. Plaintiffs' Subpoena Seeks Irrelevant Information and Is Not Reasonably Calculated to Lead to the Discovery of Admissible Evidence.

Given that discovery is appropriately limited to those facts relevant to the claims and defenses identified in the pleadings in this action, Synthes objects to the subpoena on the grounds that the document requests are not reasonably calculated to lead to the discovery of admissible evidence and are not relevant to the subject matter of the action.

The documents and information sought in Plaintiffs' Subpoena have no relevance to the claims and defenses in this alleged product liability action and are not reasonably calculated to lead to the discovery of admissible evidence. Plaintiff Calvin Timberlake was never treated by Dr. Peppers or anyone affiliated with Core Orthopedic Medical Center. Instead, Dr. Peppers was an investigator in the FDA-approved clinical trial of the ProDisc prior to its approval by the FDA. Plaintiff Calvin Timberlake was not a participant in the clinical trial of the ProDisc and was implanted with the ProDisc after its approval by the FDA. Thus, the requested documents deal exclusively with patients and information not involved in this litigation. Accordingly, the requested information is being sought solely to unduly burden and oppress Synthes and these third party healthcare providers involved in the FDA-approved clinical trial of the ProDisc. When, as here, a subpoena is "served for the purpose of annoying and harassment and not really for the purpose of getting information," it should be quashed. *Mattel Inc. v. Walking Mountain Productions*, 353 F.3d 792 (9th Cir. 2003) (affirming the district court's decision to quash an overbroad and oppressive non-party subpoena).

Further, Plaintiffs' requests generally focus on financial information and relationships of the investigators in the FDA-approved clinical trial of the ProDisc. It is the role of the FDA, however, and not Plaintiffs, to monitor the financial interest or relationships of the investigators. *See, e.g.*, 21 C.F.R. § 812.119 (providing for disqualification of clinical investigators). The Supreme Court has held that there is no private right of action to challenge this role of the FDA, because these types of actions "inevitably conflict with the FDA's responsibility to police fraud ..." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).[4] In short, none of the private information sought by Plaintiffs is relevant to any viable cause of action nor can it lead to information that would be relevant to any such claim.

---

[4] Plaintiffs' requested documents are also irrelevant to the underlying suit and cannot lead to the discovery of relevant information because: (1) the financial information requested is not relevant to the device approval process, (2) once a device is approved by the FDA, causes of action based on pre-approval submissions or non-submissions are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); and (3) all the causes of actions at issue are preempted, as a matter of law, by *Riegel v. Medtronic, Inc.*, No. 06-179, 552 U.S. ___ (Feb. 20, 2008). Synthes reserves its right to file a motion for summary judgment or other dispositive motion on the grounds that Plaintiffs' claims against it are preempted.

The requested documents have absolutely no relevance to the case at hand. However, production of these documents would inject irrelevant and potentially inflammatory information into this case, would divulge confidential information about unrelated parties' investments and finances, which have no effect on or relationship with Plaintiffs and have nothing to do with Plaintiff's care. The unreasonable injection of the Physicians' investment and financial information has no bearing on this case and is highly prejudicial to Synthes and its ability to conduct clinical trials. On balance, therefore, this Court should forbid, or at least limit in scope, Plaintiffs' overly broad and unduly burdensome subpoena. *See Anderson v. Abercrombie and Fitch Stores, Inc.*, No. 06 CV 991, 2007 WL 1994059, at *2 (S.D. Cal. July 2, 2007) (*quoting Moon v. SCP Pool Corp.*, 232 F.R.D. 633, 637 (C.D. Cal. 2005) ("'An evaluation of undue burden requires the court to weigh the burden to the subpoenaed party against the value of the information to the serving party[,]' and mandates the court's consideration of such factors as relevance, the serving party's need for the requested documents, the breadth of the discovery request, the particularity with which the documents are described and the burden imposed.").

D. Plaintiffs' Subpoena Seeks Confidential Trade Secret Information.

Federal Rule of Civil Procedure 45(c)(3)(B)(i) specifically explains that a court should quash or modify a subpoena if it "requires disclosure of a trade secret or other confidential research, development, or commercial information." Courts in this Circuit have consistently quashed subpoenas that seek disclosure of trade secrets or other confidential information in contravention of the Federal Rules of Procedure. *See, e.g., Anderson v. Abercrombie and Fitch Stores, Inc.*, No. 06 CV 991, 2007 WL 1994059 (S.D. Cal. July 2, 2007); *Wood v. Vista Manor Nursing Ctr.*, No. 06-01682, 2007 WL 832933 (N.D. Cal. March 16, 2007); *Compaq Computer Corp. v. Packard Bell Electronics, Inc.*, 163 F.R.D. 329 (N.D. Cal. 1995);

The document requests outlined in the Subpoena require the disclosure of a trade secret or confidential research, development, or commercial information. Further, the document requests have the distinct potential to inhibit Synthes' commercial growth and competitive advantage in the marketplace by disclosing protected trade secrets and confidential proprietary information and revealing privileged information about individual patients. All nine requests specifically seek information that has not been released to the public and that is proprietary and confidential information to Synthes. For instance, Plaintiffs' request that the third parties produce "all correspondence that relates to ProDisc between you and any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc." *See* Plaintiffs' Subpoena, Exhibit B. This overly broad request, unlimited in time or scope to the care and treatment of Plaintiff Calvin Timberlake, requires Dr. Peppers and the medical institutions with which he works to reveal Synthes' proprietary clinical trial design, protocol, and implementation documents related to the FDA-approved clinical trial of the ProDisc in the possession of Dr. Peppers. This is just one example of Plaintiffs' numerous, over-reaching requests that these third parties cannot answer without divulging Synthes' confidential and protected information in direct contravention of Federal Rule of Civil Procedure 45(c)(3)(B)(i).

E. Plaintiffs' Subpoena Seeks Confidential Patient Information.

Plaintiffs' requests seek confidential patient information that is protected from disclosure by both the privacy regulations issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the patient-physician privilege. Specifically, through their subpoena, Plaintiffs seek:

> 6. All documents you filed with or provided to the Food and Drug Administration that discuss mention or in any way relate to ProDisc.
>
> 8. All correspondence between you and the FDA that relate in any way to ProDisc.
>
> 9. All correspondence that relates to ProDisc between you and any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc.

Plaintiffs' Subpoena, Exhibit B.

These requests violate the purpose and intent of both HIPAA and New York's physician-patient privilege. HIPAA demonstrates that "'[p]rivacy is a fundamental right' and that '[a] right to privacy in personal information has historically found expression in American law.'" *U.S. v. Comprehensive Drug Testing, Inc.*, 513 F.3d 1085, 1138 (9th Cir. 2008) (Thomas, J., *concurring in part, dissenting in part*). To that end, "[w]hile privacy is one of the key values on which our society is built, it is more than an end in itself. It is also necessary for the effective delivery of healthcare, both to individuals and to populations . . . the need for privacy of health information, in particular, has long been recognized as critical to the delivery of needed medical care." 65 Fed.Reg. 82462, at 82,467. Accordingly, HIPAA forbids healthcare providers and other "covered entities" from using or disclosing an individual's protected health information in response to a request for production of documents in litigation without (1) a HIPAA-compliant authorization; (2) a court order; or (3) certain satisfactory assurances accompanied by a proper request for production. *See* 45 C.F.R. 160.103, 164.104(a), 164.502(a).

By seeking documents filed with or provided to the FDA regarding these Third-Parties involvement in clinical trials of the ProDisc, Plaintiffs' Subpoena necessarily seeks protected healthcare information of all the individual patients under Dr. Peppers' care during the clinical trials, none of whom are in any way related to this case and none of whom have authorized the release of their confidential information. Plaintiffs' Subpoena, however, was not accompanied by authorizations from Dr. Peppers' patients or a court order. Further, Plaintiffs failed to provide the necessary satisfactory assurances along with their Subpoena. Thus, to the extent that Plaintiffs' Subpoena requests individual healthcare information from these third party healthcare providers, the HIPAA Privacy Rule forbids their production.

Additionally, the physician-patient privilege exempts privileged information from disclosure. "The physician-patient privilege embraces more than verbal communication; it extends to information obtained by an examination of the patient and includes the physician's diagnosis and advice." *Blue Cross of Northern California v. Superior Court of Yolo County*, 61 Cal.App.3d 798, 800, 132 Cal.Rptr. 635, 636 (1976). Privileges, such as the physician-patient privilege, were created because "it is more important to keep certain information confidential than it is to require disclosure of all information relevant to the issues in the lawsuit." *Palay v. Superior Court of Los Angeles County*, 18 Cal.App.4th 919, 927, 22 Cal.Rptr.2d 839, 844 (1993). Further, only the patient, or his guardian or executor, as the holder of the privilege, may authorize waiver of this privilege. *See id.*

Accordingly, any medical information about specific patients who underwent the clinical trials and received care from the third party healthcare providers is not subject to discovery and Plaintiffs' request for these documents should be quashed.

CONCLUSION

Synthes does not contest Plaintiffs' right to seek discovery from third parties, as a general premise. That discovery, however, must be conducted at the appropriate time, be relevant to this litigation, serve a legitimate purpose and be conducted without exposing to the public confidential trade secrets or patients' protected health-care information. Here, Plaintiffs' overly broad and improper requests do not serve such purposes.

Accordingly, Synthes respectfully requests that the Court quash Plaintiffs' third party subpoena. Alternatively, Synthes respectfully requests that the Court stay any ruling on the subpoena until the parties' home district rules on Defendants' Motion for Protective Order.

Dated: March 27, 2008 GREENBERG TRAURIG, LLP

By [signature]
Lisa L. Halko
Kathleen E. Finnerty
Attorneys for Defendants
Synthes Spine Company, L.P.
and Spine Solutions, Inc.

OF COUNSEL:

Lori G. Cohen
Georgia State Bar No. 174455
Christiana C. Jacxsens
Georgia State Bar No. 233912
GREENBERG TRAURIG, L.L.P.
The Forum
3290 Northside Parkway, Suite 400
Atlanta, GA 30327
(678) 553-2100 - Telephone
(678) 553-2212 – Facsimile

Attorneys for Defendants
Synthes Spine Company, L.P.
and Spine Solutions, Inc.

CERTIFICATE OF CONFERENCE

I certify that on March 26th, 2008, via a telephone conversation I conferred in good faith with counsel for Plaintiffs as to this Motion regarding Plaintiffs' third party subpoenas in an effort to resolve the dispute without court action. Counsel for Plaintiffs indicated that they were opposed to this Motion.

s/ Christiana Jacxsens
Christiana Jacxsens

CERTIFICATE OF SERVICE

I am a citizen of the United States, over the age of 18 years, and not a party to or interested in this action. I am an employee of Greenberg Traurig LLP, and my business address is 1201 K Street, Suite 1100, Sacramento, CA 95814. On this day I caused to be served the following document(s):

DEFENDANT SYNTHES SPINE COMPANY, L.P.'S BRIEF IN SUPPORT OF ITS MOTION TO QUASH OR, IN THE ALTERNATIVE, STAY PLAINTIFFS' THIRD-PARTY SUBPOENA ON TIMOTHY A. PEPPERS, M.D. AND CORE ORTHOPEDIC MEDICAL CENTER

☐ By placing a true copy, in a sealed envelope, with postage fully prepaid, in the United States Post Office mail at Sacramento, California, addressed as set forth below. I am familiar with this firm's practice whereby the mail, after being placed in a designated area, is given the appropriate postage and is deposited in a U.S. mail box after the close of the day's business.

☐ By personal delivery of a true copy to the person and at the address set forth below.

☒ By Federal Express Mail to the person and at the address set forth below.

☐ By transmitting via ELECTRONIC MAIL (EMAIL) the document(s) listed above to the EMAIL addresses set forth below on this date at approximately ____ pm from my computer. The transmission was reported as complete and without error by the computer. I caused the computer to print a transmission record of the transmission, a copy of which is attached to the original of this declaration. The transmission report was properly issued by the transmitting computer.

James W. Cole Cole, Cole & Easley, P.C. 302 W. Forrest Street P.O. Drawer 510 Victoria, Texas 77902	Timothy A. Peppers, M.D. CORE Orthopedic Medical Center 320 Santa Fe Drive, Suite 204 Encinitas, California 92024-5179
Viscogliosi Brothers, LLC Anthony G. Viscogliosi Marc. R. Viscogliosi John J. Viscogliosi 505 Park Avenue, 14th Floor New York, New York 10022	

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on March 27, 2008, at Sacramento, California.

[signature]

IVONE CUYUN

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
VICTORIA DIVISION

CALVIN TIMBERLAKE AND KAREN TIMBERLAKE Plaintiffs	§ § §	
VS.	§ §	**CIVIL ACTION NO.** 6:08-CV-00004 **JURY REQUESTED**
SYNTHES SPINE, INC. AND SYNTHES NORTH AMERICA, INC. Defendants	§ § §	

PLAINTIFFS' FIRST AMENDED ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, **CALVIN TIMBERLAKE AND KAREN TIMBERLAKE**, Plaintiffs, complaining of **SYNTHES SPINE COMPANY, L.P., SPINE SOLUTIONS INC., VISCOGLIOSI BROTHERS L.L.C., MARC R. VISCOGLIOSI, JOHN J. VISCOGLIOSI AND ANTHONY G. VISCOGLIOSI,** herein collectively referred to as "Defendants" and would show the Court as follows:

I. Parties

1. Plaintiffs, **CALVIN TIMBERLAKE AND KAREN TIMBERLAKE**, are residents of Victoria County, Texas.

2. Defendant, **SYNTHES SPINE COMPANY, L.P.** is an entity doing business in the State of Texas. No service is necessary at this time.

3. Defendant, **SPINE SOLUTIONS INC.**, is an entity doing business in the State of Texas, and may be served with citation by serving, Anthony G. Viscogliosi, at 505 Park Avenue, 14th Floor, New York, NY 10022.

4. Defendant, **VISCOGLIOSI BROTHERS L.L.C.**, is an entity doing business in the State of Texas, and may be served with citation by serving, Anthony G. Viscogliosi, at 505 Park Avenue, 14th Floor, New York, NY 10022.

5. Defendant, **MARC R. VISCOGLIOSI,** is an individual resident of the State of New York doing business in the State of Texas and may be served with citation at 505 Park Avenue, 14th Floor, New York, NY 10022.

6. Defendant, **JOHN J. VISCOGLIOSI,** is an individual resident of the State of New York doing business in the State of Texas and may be served with citation at 505 Park Avenue, 14th Floor, New York, NY 10022.

7. Defendant, **ANTHONY G. VISCOGLIOSI,** is an individual resident of the State of New York doing business in the State of Texas and may be served with citation at 505 Park Avenue, 14th Floor, New York, NY 10022.

II. Statement of the Case

8. This is a Personal Injury - Product Liability action based in tort on the theories of common law and statutory fraud/misrepresentation, violation of the FDA approval process, negligence, strict liability for a dangerous and defective product and breach of warranty.

III. Jurisdiction

9. The Court has jurisdiction over the lawsuit under 28 U.S.C. § 1332(a)(1) because the Plaintiffs and the Defendants are citizens of different states and the amount in controversy exceeds $75,000, excluding interest and costs.

IV. Venue

10. Venue is proper in the Southern District of Texas pursuant to 28 U.S.C. § 1391 because the incident made the basis of this suit occurred in the Southern District of Texas, and the Plaintiffs resides in Victoria County in the Southern District of Texas.

V. History Regarding Plaintiff Calvin Timberlake

11. In 2005 Calvin Timberlake was a forty-nine year old fork lift driver. Mr. Timberlake had suffered back pain and undergone treatment for the back pain for several years.

12. Mr. Timberlake had been diagnosed as with degenerative disc disease of the disc between the 4th and 5th lumbar vertebras (L4-L5 disc). Mr. Timberlake had conservative treatment over a period of years which included physical therapy, medications and injections without significant relief.

13. Mr. Timberlake began researching treatment options on the Internet in consultation with his treating doctor. Mr. Timberlake learned of an artificial disc called the ProDisc, which could be inserted in place of the degenerated disc, and which artificial disc was then and is still now manufactured by or on behalf of Synthes Spine Company, L.P. The surgery involved removing the degenerated disc. The artificial disc consist of two metal ends which are attached to the vertebrae above and below the removed disc and a polypropylene insert that was placed between the two end plates.

14. When Mr. Timberlake learned of the ProDisc it had not been approved by the Food and Drug Administration (FDA) but was undergoing clinical trials. Mr. Timberlake read multiple reports of the successes of the ProDisc artificial disc trials. Mr. Timberlake read that the ProDisc had been through rigorous testing conducted by numerous doctors with fantastic results. Included in the doctors and clinics conducting the clinical trials was one presided over

by Dr. Jack Zigler at The Texas Back Institute in Plano, Texas. (At this time Mr. Timberlake was totally unaware that many of the doctors performing the trials, including Dr. Zigler, were investors in Spine Solutions Inc. – either directly or as investors in funds that invested in the company – and those doctors thereby had a large financial interest in the outcome of the trials.)

15. Mr. Timberlake read claims by Dr. Zigler that he had presided over the study of the ProDisc. Dr. Zigler and others claimed the ProDisc had been found to result in significantly better outcomes than the alternative treatments. Mr. Timberlake read claims made by the defendants, and substantiated by the doctors performing the studies that the ProDisc would provide him a faster recovery and allow him to return to work faster. Defendants intentionally caused physicians implanting the device, the public, the FDA and Mr. Timberlake to erroneously believe that the studies were independent studies, performed by disinterested physicians. In reality, however, many of the physicians performing the studies and making the representations had a financial interest in the results of the studies.

16. In addition to being unaware that many of the doctors participating in the clinical trials had a financial outcome, he was unaware that the doctors had intentionally left out of the reported results of the studies a large number of patients who had received implantation of the ProDisc, many of whom, upon information and belief, had outcomes less favorable than those that were included in the reports of the studies. Mr. Timberlake was also unaware that there was no acceptable salvage surgery in the event that the artificial disc failed and that removing a failed artificial disc would be a life threatening surgery.

17. Based on the representations made by the defendants and the doctors who performed the studies, including Dr. Zigler, on June 20, 2006, Mr. Timberlake saw Dr. Christoph Meyer at the Houston Center for Spinal Reconstruction and Disc Replacement, for the purpose

of discussing implantation of the ProDisc artificial disc. Mr. Timberlake was informed the ProDisc had not been approved by the FDA but it should be in the near future. Mr. Timberlake elected to delay any surgery until such time that the ProDisc received FDA approval.

18. On August 14, 2006, the FDA approved the ProDisc for use.

19. On or about December 14, 2006, Calvin Timberlake had lumbar spinal surgery at the L4-L5 level at Foundation Surgical Hospital in Bellaire, Texas, performed by Dr. Christoph Meyer. The surgery consisted of a total disc replacement using a ProDisc which was manufactured and sold by Defendants.

20. On December 19, 2006, five days after the disc was implanted, x-rays revealed it had completely failed.

21. On April 4, 2007, less than four months after having the ProDisc implanted, Calvin Timberlake underwent a salvage operation to remove the failed ProDisc artificial disc. The disc was found to have come completely apart. The polypropylene insert in the disc had become dislodged from the metal end plates and attached to the iliac vein. Vascular surgeon, Dr. Mickey Morgan M.D. performed the multi-hour surgery attempting to gain control of the bleeding of the vein. After three hours of attempting to gain control of the bleeding, Dr. Morgan called in a second vascular surgeon to assist him because of the difficulty of gaining control of the bleeding. Once the bleeding was controlled, the end plates of the failed ProDisc were removed.

22. Because of the complications in the surgical removal, the surgeon was unable to complete the fusion at that time. On April 10, 2007 Mr. Timberlake was returned to surgery where the fusion of the L4 and L5 vertebras was completed with the insertion of hardware.

23. The failure of the ProDisc resulted in bilateral fractures of the vertebral pedicles at L4 and permanent disabling pain.

VI. History Regarding ProDisc,

Viscogliosi Brothers L.L.C., Marc R. Viscogliosi, John J. Viscogliosi, Anthony G. Viscogliosi, Spine Solutions Inc. and Synthes Spine Company, L.P.

24. In the late 1980s, a French physician named Dr. Thierry Marnay, designed an artificial inter-vertebral disc now known as the ProDisc. A French company, Aesculap AG & Co. KG, obtained the rights to the ProDisc.

25. In 1999 Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi established Viscogliosi Brothers L.L.C. in New York City as a venture capital/private equity and merchant banking firm.

26. That same year, 1999, Viscogliosi Brothers L.L.C. (VB) and Aesculap AG & Co. KG formed Spine Solutions, Inc. The goal of Spine Solutions Inc. was the commercialization of the ProDisc artificial disc. Under the terms of the joint venture, VB furnished the capitalization and Aesculap contributed the patents and related intellectual property rights to the ProDisc technology.

27. VB, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi predicted the newly developed artificial disc would grow to a $3 billion market by 2008 and a $12 billion market by 2010.

28. It was the position of VB, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi that once the ProDisc reached "semi-advanced technology" status Spine Solutions Inc. would be purchased by one of three large medical device manufacturers, resulting in a

substantial profit. To become marketable, the ProDisc needed to reach preliminary approval by the FDA and be in clinical trials.

29. Developing and testing the ProDisc was extremely expensive. To obtain the necessary financing Spine Solutions Inc., VB, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi, hired a team of employees and consultants to, along with Spine Solutions, Inc., VB, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi, solicit investors. As part of the process VB, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi also formed at least four different investment funds that would invest in Spine Solutions Inc., including: Spine Solutions Partners, Spinal Partners I. Spinal Partners II and Spinal Partners III.

30. By at least as early as May of 2001, VB, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi were all in extremely dire financial condition. Capital had been exhausted. On information and belief, the principals in VB, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi began embezzling investor funds in order to pay their personal and business expenses as well as to support their personal lavish lifestyle.

31. In or about September of 2002, the Federal Bureau of Investigation (FBI), The United States Attorney's Office, New York State Attorney General's Office and the Manhattan District Attorney's Office became aware that Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi, the principals in VB, were embezzling investor funds and a criminal prosecution was begun.

32. VB, through Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi, communicated to its employees and consultants that unless Spine Solutions Inc. and ProDisc could be sold very rapidly, everyone would be out of a job.

33. VB principals, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi were faced with a criminal investigation and possible criminal indictment.

34. VB and its principals, Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi were under tremendous pressure to achieve ProDisc implantations, get FDA approval, and sell Spine Solutions Inc. to obtain funds to repay the embezzled funds to prevent financial ruin and likely criminal indictment.

VIII. Doctors performing Clinical Trials "in our pocket"

35. In an attempt to protect themselves from financial ruin and criminal indictment VB, Marc R. Viscogliosi, John J. Viscogliosi, Anthony G. Viscogliosi and Spine Solutions Inc. instructed their employees and consultants to seek physicians who would agree to invest in the companies and at the same time participate in the clinical trials required for FDA approval. These actions were taken without regard for the scientific validity of the outcome of the studies or the health of patients who were then or later implanted with the ProDisc.

36. Officers of both VB and Spine Solutions Inc., including Marc R. Viscogliosi, John J. Viscogliosi and Anthony G. Viscogliosi, stated that by having doctors participating in the trials while investing in the company would result in (A) more readily obtaining additional investors and (B) having the doctors doing the trials "in our pocket" and thereby ensure an outcome favorable to the defendants. VB, its principals, and Spine Solutions Inc. thereby knowingly and intentionally set up an inherent conflict between the investor/doctors performing the trials and the reporting of results adverse to their personal financial interest.

37. On October 3, 2001, the first implant of a ProDisc in the U.S. was performed as part of clinical trials at The Texas Back Institute in Plano, Texas by Dr. Jack Zigler. No disclosure was made to the FDA, the public, physicians or to Calvin Timberlake that The Texas

Back Institute, Dr. Zigler and other physicians practicing at the Texas Back Institute were investors and would gain financially if the ProDisc was approved by the FDA.

38. VB and Spine Solutions Inc. were successful in locating approximately a dozen doctors and clinics who agreed to invest in the company while also participating in the clinical trials.

39. On January 7, 2003, Spine Solutions reported a "rapid growth in ProDisc qualified surgeons in 2002."

40. On or about February 6, 2003 Synthes agrees to purchase Spine Solutions Inc. for $350,000,000. Synthes agreed to pay $175,000,000 at closing and another $175,000,000 upon FDA approval.

41. During the time that Calvin Timberlake was considering and evaluating the ProDisc, and thereafter while he was awaiting its FDA approval, so that he could receive the ProDisc, it was never disclosed to him that many of the doctors performing the clinical trials that he was waiting to be completed stood to share in $175,000,000 if the approval came through.

42. Defendants made misrepresentations and intentionally provided incomplete and erroneous information to the FDA, patients, non-investing doctors and the general public regarding the clinical trials, the performance capabilities of the ProDisc, the safety of the ProDisc, problems with the disc's design and performance.

43. Defendants made intentional express representations to doctors, patients, the general public and Calvin Timberlake regarding the disc that exceeded the performance capabilities presented by the defendants to the FDA. These representations were false and were intended to induce persons such as Calvin Timberlake to have a ProDisc implanted. As a result of the representations Calvin Timberlake had the ProDisc implanted.

44. On information and belief, Synthes was aware, prior to approval of the ProDisc by the FDA and prior to a ProDisc being implanted in Calvin Timberlake, of the improprieties committed by VB, Marc R. Viscogliosi, John J. Viscogliosi, Anthony G. Viscogliosi and Spine Solutions Inc., in intentionally soliciting doctors to invest in ProDisc and participate in the trials knowing there was an inherent conflict created by using doctors who were investors whom stood to gain financially from the outcome of the trials. Synthes was also aware of the allegations of embezzlement of investor funds by VB, Marc R. Viscogliosi, John J. Viscogliosi, Anthony G. Viscogliosi prior to approval of the ProDisc by the FDA and prior to a ProDisc being implanted in the Calvin Timberlake.

45. In February of 2008 the New Jersey Attorney General issued subpoenas to Synthes Spine Inc. and Viscogliosi Brothers L.L.C. seeking information from January 1, 1999 through the present. The subpoenas seek information concerning physicians who had invested in ProDisc also participating in, and the results of, clinical studies of ProDisc.

VIII

Count I – Fraud/ Misrepresentation

46. Plaintiffs incorporate all other paragraphs of this complaint as if fully set forth herein.

47. Defendants made the following intentional, material misrepresentations and committed fraud in:

a. Intentionally misrepresenting and failing to disclose to the FDA, to the public, to surgeons who were not investors in the companies, and to Calvin Timberlake that doctors and clinics that were participating in the clinical trials would benefit financially if the FDA approved the device and from the sale of the devices; and

b. Intentionally misrepresenting and failing to disclose to the FDA, to the public, to surgeons who were not investors in the companies, and to Calvin Timberlake that Dr. Jack Zigler, the lead investigator for the ProDisc FDA trials and the lead author on published results and his clinic, The Texas Back Institute and other doctors at the Texas Back Institute would benefit financially if the FDA approved the device and would benefit from the sale of the devices; and

c. Intentionally misrepresenting the nature, history and result of the clinical trials; and

d. Intentionally providing to the FDA, to the public, to physicians, and to Calvin Timberlake, incomplete and misleading information concerning its clinical trials; and

e. Intentionally making false representations to the FDA, to the public, to physicians, and to Calvin Timberlake regarding the performance capabilities of the ProDisc; and

f. Intentionally failing to disclose to the FDA, to the public, to physicians, and to Calvin Timberlake problems with ProDisc's design and performance; and

g. Intentionally making express representations to doctors, patients and the general public concerning ProDisc safety and effectiveness, which exceeded the performance capabilities presented by the defendants to the FDA; and

h. Intentionally making express, representations to doctors, patients and the general public which were never considered by the FDA.

48. The intentional misrepresentations set forth above were done to induce Calvin Timberlake to have the ProDisc implanted and to induce his physician to implant the ProDisc.

49. The misrepresentations set forth were done intentionally with knowledge they were false when made.

50. Calvin Timberlake justifiably relied on the misrepresentations in his decision to have the ProDisc implanted.

51. Plaintiffs sustained injuries and damages as set forth below as a proximate result of the fraud and misrepresentations.

Count II – Negligence

52. Plaintiffs incorporate all other paragraphs of this complaint as if fully set forth herein.

53. Plaintiffs plead further and in the alternative that Plaintiffs' injuries were directly and proximately caused by the negligence of the Defendants. At the time and place in question, Defendants were guilty of many acts of negligence, each of which jointly and severally proximately caused the serious injuries suffered by Plaintiffs. Plaintiffs allege Defendants were negligent in the manufacturing and the labeling of the ProDisc and in addition that the manufacture and labeling were not as approved by the FDA and as such violated federal law.

54. Plaintiffs allege the Defendants negligently failed to comply with the process set forth by the FDA for approval of medical devices such as the ProDisc. This failure was done with conscious disregard for those who would have the ProDisc implanted in the future.

55. Plaintiffs allege that the Defendants and/or their agents, servants, and/or employees were negligent in designing, manufacturing, labeling and marketing the ProDisc involved in the occurrence in question. Defendants were negligent in various acts and omissions, which negligence was the proximate cause of the occurrence in question.

56. Plaintiffs sustained injuries and damages as set forth below as a proximate result of the negligence of the Defendants.

Count IV - Strict Liability in Tort-Products

57. Plaintiffs incorporate all other paragraphs of this complaint as if fully set forth herein.

58. Plaintiffs allege that the ProDisc as manufactured, designed, labeled and marketed by Defendants, was defective and unsafe for its intended use. Plaintiffs allege the ProDisc that was implanted in Calvin Timberlake was not manufactured and labeled as approved by the FDA. In this connection, the ProDisc was unreasonably dangerous to Calvin Timberlake. Plaintiffs therefore invoke the doctrine of strict liability in §82.001 et seq. of the Texas Civil Practice and Remedies Code and Restatement (second) of the Law of Torts 4.01A and as adopted by the Supreme Court of Texas. Further, in this connection, Plaintiffs allege that the defects of the ProDisc were producing causes of the injuries and damages set forth below.

59. Plaintiffs allege Defendants circumvented the Pre-Marketing Approval process set out by the FDA. Plaintiffs allege the Defendants provided financial incentives to physicians who were performing the pre-marketing testing and evaluation. Plaintiffs allege providing financial incentives to physicians performing the testing and evaluation is a direct violation of the FDA approval process or in the alternative a violation of the implied purpose of the FDA Pre-Market Approval process.

60. The circumvention of the Pre-Market Approval process by the Defendants allowed the Defendants to market in the United States a device that is inherently dangerous.

61. Plaintiffs allege that the defects of the ProDisc were producing causes of the injuries and damages set forth below.

Count VI - Breach of Warranty

62. Plaintiffs incorporate all other paragraphs of this complaint as if fully set forth herein.

63. In addition, the Defendants made express warranties to the public generally, and specifically to Plaintiffs. The Defendants breached the warranties. Plaintiffs relied upon these express warranties. Plaintiffs sustained injuries and damages as set forth below as a proximate result of the breach of these warranties.

Count VI - Conspiracy

64. Plaintiffs incorporate all other paragraphs of this complaint as if fully set forth herein.

65. Defendants acted together to perpetuate an unlawful conspiracy to the damage of the Plaintiffs. Defendants had knowledge of, agreed to, and intended a common objective or course of action that resulted in damage to the Plaintiffs as set forth below.

66. From the inception, the Defendants were aware of the harm to patients such as Calvin Timberlake that would likely result from their conduct.

IX. Damages

67. As result of the above described, Calvin Timberlake, suffered severe personal injuries causing him to sustain permanent bodily impairment, disfigurement, loss of earning capacity in the past, and a loss of earning capacity in the future. Mr. Timberlake has experienced physical pain and mental anguish and will, in reasonable probability, continue to do so in the future. Mr. Timberlake has been caused to incur medical charges and expenses in the past and will continue to incur medical expenses in the future for his injuries.

68. Prior to and at the time of the accident made the basis of this suit, Plaintiffs, Calvin Timberlake and Karen Timberlake, were husband and wife, and enjoyed a fulfilling and happy marriage relationship. As a result of the negligence of the Defendants, and the consequent injuries suffered by Calvin Timberlake, Plaintiff Karen Timberlake, has suffered a substantial loss of consortium, and has suffered a substantial impairment of the affection, solace, comfort, companionship, society, assistance and sexual relations necessary to a successful marriage. Plaintiff, Karen Timberlake has suffered grief and mental anguish, loss of contributions, both by way of money and advise, labor, services, and counsel and has been damaged as a result thereof in an amount greater than the minimum jurisdictional amount of this Court for which amount she now sues.

X. Exemplary Damages

69. The above-referenced acts and/or omissions, when viewed objectively from the standpoint of the Defendants at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of potential harm to others, and were of such a nature that Defendants had, or should have had, a subjective awareness of the risks involved, but nevertheless proceeded with malice and conscious indifference to the rights, safety, and welfare of others, including but not limited to the Plaintiffs. Plaintiffs hereby invoke the benefits and protection of Chapter 41 (TCPRC).

XI. Jury Demand

70. By reason of the above and foregoing, Plaintiffs has been damaged in a sum in excess of the minimum jurisdictional limits of this Court.

71. WHEREFORE, Plaintiffs pray that the Defendants be duly cited to appear and answer herein; that upon a final trial of this cause, Plaintiffs will recover:

1. Judgment against Defendants for Plaintiffs' damages as set forth above, in an amount in excess of the minimum jurisdictional limits of this Court;
2. Interest on said judgment at the legal rate from date of judgment;
3. Pre-judgment interest as allowed by law;
4. Costs of Court; and
5. Such other and further relief to which Plaintiffs may be entitled.

Respectfully submitted,

COLE, COLE & EASLEY, P.C.
302 W. Forrest Street
PO Drawer 510
Victoria, Texas 77902
Phone: (361) 575-0551
Fax: (361) 575-0986

By: ____________________
JIM COLE
State Bar No. 04538500
Federal I.D. No. 5883
Rex Easley Jr.
State Bar No. 06358425
Federal I.D. No. 5886
William L. Sciba Jr.
State Bar No. 00792824
Federal I.D. No. 19044

CERTIFICATE OF SERVICE

By my signature above, I certify that a true and correct copy of the foregoing instrument was delivered to all counsel of record in accordance with the applicable Federal Rules of Civil Procedure on this the 21 day of February, 2008.

EXHIBIT B

AO88 (Rev. 12/07) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

Southern District of California

Calvin Timberlake and Karen Timberlake

V.

Synthes Spine, Inc. and Synthes North America, Inc.

SUBPOENA IN A CIVIL CASE

Case Number:[1] 6:08-CV-00004(S.D. Tex)

TO: Timothy A. Peppers, M.D.
CORE Orthopedic Medical Center
320 Santa Fe Drive, Suite 204
Encinitas, CA 92024-5179

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☐ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME

☑ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

320 Santa Fe Drive, Suite 204
Encintis, CA 92024-5179
or another location agreed to by the parties

PLACE	DATE AND TIME

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rule of Civil Procedure 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
Attorney for Plaintiff	3/13/2008

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Jim Cole, Cole, Cole & Easley, P.C.
302 W. Forrest, P.O. Box 510, Victoria, Texas 77902 Telephone Number: 361-575-0551

(See Federal Rule of Civil Procedure 45 (c), (d), and (e), on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

EXHIBIT B
Page 1 of 6

AO88 (Rev. 12/07) Subpoena in a Civil Case (Page 2)

PROOF OF SERVICE

	DATE	PLACE
SERVED		

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on ____________________ DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

Federal Rule of Civil Procedure 45 (c), (d), and (e), as amended on December 1, 2007:

(c) PROTECTING A PERSON SUBJECT TO A SUBPOENA.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) When Required. On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) DUTIES IN RESPONDING TO A SUBPOENA.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) CONTEMPT.

The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

EXHIBIT B
Page 2 of 6

EXHIBIT "A"

INSTRUCTIONS

1. Singular and masculine forms of any nouns or pronouns shall embrace and be applied as the plural or as the feminine or neuter, as appropriate to the context, and vice-versa.

2. Each category is to be construed and responded to independently and not to be referenced to any other item herein for purposes of limitation.

3. Documents produced pursuant to this request should be tendered either in the precise form or manner as they are kept in the usual course of business or organized and labeled to correspond with the categories which follow.

4. If you (or any of your representatives, attorneys or agents) have ever had any of the documents requested in your possession, custody or control, but at the present do not have these documents in your possession, custody or control, you are requested to state the following with respect to each such document or material:

   a. The present location thereof, if known;
   b. The date each such document or material left your possession, custody or control;
   c. The reasons why each such document or material left your possession, custody or control; and
   d. The names and addresses of all persons having knowledge about the matters inquired about in the immediately preceding subparagraphs a - c.

5. If any document or material requested herein has been destroyed or lost, you are requested to describe in detail the circumstances of, and the reasons for, such destruction or loss and to produce all documents which relate to either the circumstances or the reasons for such destruction or loss.

DEFINITIONS

1. As used herein, the terms "you" or "your" shall mean TIMOTHY A. PEPPERS, M.D. and/ or CORE ORTHOPEDIC MEDICAL CENTER and its present or former agents, representatives, attorneys, present or former officers, directors, agents, representatives, employees or other persons acting on its behalf, including any other person or entity which acquired stock, assets or liability of CORE ORTHOPEDIC MEDICAL CENTER or any other person or entity acting on behalf, singularly or combined.

2. As used herein, the term "person" shall mean and include any individual association, firm, partnership, corporation, trust, board, committee, company, agency or commission, or any other legal entity of any type, or any other organization or entity, whether public or private.

3. The term "documents" shall mean all writings of every kind, source, and authorship, both originals and all nonidentical copies thereof, in your possession, custody, or control, or known by you to exist, irrespective of whether the writing is one intended for or transmitted internally by you, or intended for or transmitted to any other person or entity, including without limitation any government agency, department, administrative, or private entity or person. The term shall include handwritten, typewritten, printed, photocopied, photographic, or recorded matter. It shall include communications in words, symbols, pictures, sound recordings, films, tapes, and information stored in, or accessible through, computer or other information storage or retrieval systems, together with the codes and/or programming instructions and other materials necessary to understand and use such systems. For purposes of illustration and not limitation, the term shall include: affidavits; agendas; agreements; analyses; announcements; bills; statements; and other records of obligations and expenditures; books; brochures; bulletins; calendars; canceled checks; vouchers, receipts and other records of payments; charts, drawings; check registers; checkbooks; circulars; collateral files and contents; contracts; corporate by-laws; corporate charters; correspondence; credit files and contents; deeds of trust; deposit slips; diaries; drafts; files; guaranty agreements; instructions; invoices; ledgers, journals, balance sheets, profit and loss statements, and other sources of financial data; letters; logs, notes or memoranda of telephonic or face-to-face conversations; manuals; memoranda of all kinds, to and from any persons, agencies, or entities; minutes; minute books; notes; notices; parts lists; papers; press releases; printed matter (including published books, articles, speeches, and newspaper clippings); purchase orders; records; records of administrative, technical, and financial actions taken or recommended; reports; safety deposit boxes and contents and records of entry; schedules; security agreements; specifications; statement of bank accounts; statements, interviews; stock transfer ledger; technical and engineering reports, evaluations, advice, recommendations, commentaries, conclusions, studies, test plans, manuals, procedures, data, reports, results, and conclusions; summaries, notes, and other records and recordings of any conferences, meetings, visits, statements, interviews or telephone conversations; telegrams, teletypes and other communications sent or received; transcripts of testimony; UCC instruments; work papers; and all other writings, the

contents of which relate to, discuss, consider, or otherwise refer to the subject matter of the particular discovery requested.

4. As used here in "ProDisc" shall mean the total disc replacement medical device currently manufactured by Synthes or any predecessor of that medical device.

5. "Any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc" includes but is not limited to entities with "Spine Solutions," "Spine Partners," "Spine Solutions Partners, " "Spinal Partners," Viscogliosi" or any variation or combination of those names.

DOCUMENT REQUEST

1. All documents relating to your investment, or potential investment, in any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc, including but not limited to, correspondence, solicitations, investor packets, stock certificates, ownership certificates, shareholder agreements, and loan documents.

2. All financial documents relating to your investment in, purchase or sale of your ownership interest in any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc, including but not limited to, bank records, canceled checks, income tax returns and loan documentation.

3. All documents relating to any agreements with any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc, to perform, clinical trials or other trials relating to the ProDisc.

4. All financial documents pertaining to your agreement with any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc, to perform clinical trials or other trials on the ProDisc.

5. All documents relating to your relationship with Synthes, Inc. or any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc, including but not limited to stock ownership, and agreements to market, sell or implant ProDisc.

6. All documents you filed with or provided to the Food and Drug Administration that discuss mention or in any way relate to ProDisc.

7. All documents filed with or provided to the FDA that discloses, discusses or denies that you have or had an ownership interest in any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc that has or had a financial interest in ProDisc.

8. All correspondence between you and the FDA that relate in any way to ProDisc.

9. All correspondence that relates to ProDisc between you and any company or entity known to you or believed by you to have any relationship, ownership or other involvement with ProDisc.

Anthony Alloy

From: cuyuni@gtlaw.com
Sent: Friday, March 28, 2008 8:04 AM
To: Anthony Alloy
Subject: FW: Synthes/Timberlake: Assistance with Motions to Quash
Attachments: Linovitz.PDF; Peppers.PDF; Zucherman.PDF

Anthony, here are the pleadings we would like you to file for us today.

Two are in the Southern District and one is in the Northern.

Please call if you have any questions.

Thanks.

Ivone Cuyun
Legal Assistant to
Lisa L. Halko and
Jeremy A. Meier
Greenberg Traurig, LLP
1201 K Street, Suite 1100
Sacramento, CA 95814
Phone (916) 442-1111
Fax (916) 448-1709
email: cuyuni@gtlaw.com

Greenberg Traurig, LLP is an international, full-service law firm with more than 1750 attorneys and governmental affairs professionals in the U.S. and Europe. The firm was selected as the 2007 USA Law Firm of the Year by Chambers and Partners.

From: Jacxsens, Christiana (Assoc-Atl-LT)
Sent: Thursday, March 27, 2008 3:32 PM
To: Halko, Lisa (Shld-Sac-LT)
Cc: Finnerty, Kathleen (Shld-Sac-LT); Cohen, Lori (Shld-Atl-LT); Lowman, W. Gary (Assoc-Atl-LT); Gordo, Jolene (Para-Sac-LT); Cuyun, Ivone (Secy-Sac-LT)
Subject: RE: Synthes/Timberlake: Assistance with Motions to Quash

No worries - it's almost Friday afterall :-)

From: Halko, Lisa (Shld-Sac-LT)
Sent: Thursday, March 27, 2008 6:19 PM
To: Halko, Lisa (Shld-Sac-LT); Jacxsens, Christiana (Assoc-Atl-LT)
Cc: Finnerty, Kathleen (Shld-Sac-LT); Cohen, Lori (Shld-Atl-LT); Lowman, W. Gary (Assoc-Atl-LT); Gordo, Jolene (Para-Sac-LT); Cuyun, Ivone (Secy-Sac-LT)
Subject: RE: Synthes/Timberlake: Assistance with Motions to Quash

Sorry --I mean AGAIN, to help the intern ...

Lisa L. Halko
Greenberg Traurig LLP
1201 K Street, Suite 1100
Sacramento, CA 95814
916-442-1111, Ext. 3010
HalkoL@GTLaw.com

From: Halko, Lisa (Shld-Sac-LT)
Sent: Thursday, March 27, 2008 3:11 PM
To: Jacxsens, Christiana (Assoc-Atl-LT)
Cc: Finnerty, Kathleen (Shld-Sac-LT); Cohen, Lori (Shld-Atl-LT); Lowman, W. Gary (Assoc-Atl-LT); Gordo, Jolene (Para-Sac-LT); Cuyun, Ivone (Secy-Sac-LT)
Subject: RE: Synthes/Timberlake: Assistance with Motions to Quash

Christiana, against to help the intern who reviews this motion, I propose that the opening paragraphs of the Peppers motion read:

COMES NOW Defendant Synthes Spine Company, L.P. ("Synthes") and files this Brief in Support of its Motion to Quash or, in the alternative, Stay Plaintiffs' Third-Party Subpoena Issued on Timothy A. Peppers, M.D. and CORE Orthopedic Medical Center pursuant to Rule 45(c)(3) of the Federal Rules of Civil Procedure. COMES NOW Defendant Synthes Spine Company, L.P. ("Synthes") and files this Brief in Support of its Motion to Quash or, in the alternative, Stay Plaintiffs' Third-Party Subpoena Issued on Jim Zucherman, M.D. pursuant to Rule 45(c)(3) of the Federal Rules of Civil Procedure.

Although this case is pending in the Southern District of Texas, the subpoena was issued by this Court, as the "issuing court" under Rule 45(c)(3)(A), the correct venue for this motion. *Fincher v. Keller Industries* 129 F.R.D. 123, 125 (M.D. NC 1990).

For the reasons set forth below, Synthes requests that the Court quash the subpoena or, alternatively, stay any required disclosures under the subpoena until after the parties' home district rules on Defendant's Motion for Protective Order, because the subpoena seeks information that is irrelevant, overly broad, privileged and confidential, and was served to unduly burden Synthes.

And Linovitz would be the same, except for the name.

OK?

Lisa L. Halko
Greenberg Traurig LLP
1201 K Street, Suite 1100
Sacramento, CA 95814
916-442-1111, Ext. 3010
HalkoL@GTLaw.com

From: Jacxsens, Christiana (Assoc-Atl-LT)
Sent: Thursday, March 27, 2008 10:37 AM
To: Halko, Lisa (Shld-Sac-LT)
Cc: Finnerty, Kathleen (Shld-Sac-LT); Cohen, Lori (Shld-Atl-LT); Lowman, W. Gary (Assoc-Atl-LT)
Subject: Synthes/Timberlake: Assistance with Motions to Quash

Lisa, I hope you are having a good morning. Thanks so much again for agreeing to help us with the filing of the Motion to Quash. I have attached for your review the finalized briefs for the Southern District and the exhibits. I will be sending along momentarily the brief for the Motion to Quash in the Northern District. Please take a look and make sure it conforms to local rules. I do not believe that Plaintiffs have obtained a case number for this, so I anticipate that we may need to obtain a new case number with the Court. If you need any additional information for this, please do not hesitate to let us know. For example, in some jurisdictions when you open up a case number, you also need to file a Certificate of Interested Persons.

Also, would it be possible for you to handle the service copies (indicated on the certificate of service)? Or if it is easier, we can handle it from here, just let me know. If you could also send to us a pdf of the file-stamped version with exhibits that would be great.

And I think I forgot to pass along yesterday the client matter number for this: 085638/010600.

Thanks so much again for all your help. I will be in the office all day today if something comes up.

Very truly yours,

Christiana

Christiana C. Jacxsens
Greenberg Traurig LLP
Suite 400-The Forum
3290 Northside Parkway
Atlanta GA 30327
(678) 553-2105 (direct phone)
(678) 553-2106 (direct fax)

Tax Advice Disclosure: To ensure compliance with requirements imposed by the IRS under Circular 230, we inform you that any U.S. federal tax advice contained in this communication (including any attachments), unless otherwise specifically stated, was not intended or written to be used, and cannot be used, for the purpose of (1) avoiding penalties under the Internal Revenue Code or (2) promoting, marketing or recommending to another party any matters addressed herein.

The information contained in this transmission may contain privileged and confidential information. It is intended only for the use of the person(s) named above. If you are not the intended recipient, you are hereby notified that any review, dissemination, distribution or duplication of this communication is strictly prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. To reply to our email administrator directly, please send an email to postmaster@gtlaw.com.

UNITED STATES
DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
SAN DIEGO DIVISION

# 149200 - SH

March 28, 2008
14:50:20

Misc. Case
USAO #.: 08MC0157
Amount.: $39.00 CK
Check#.: BC210980

Total-> $39.00

FROM: TIMBERLAKE V. SYNTHES SPINE CO